UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,306	09/20/2001	Michel Auguet	427-047	8402

47888 7590 06/14/2006

HEDMAN & COSTIGAN P.C.
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
MELLER, MICHAEL V	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,306	AUGUET ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Naftchi et al. '933 (see col. 133) or Naftchi '962 (see col. 119) for the reasons of record and for the reasons which follow.

Applicant argues that the patents disclose a reaction product of two compounds. While this may be true, they still do start with the two compounds lipoic acid and aminoguanidine, see col. 133, under number 208, of Naftchi '933 and col. 119 of Naftchi '932. In Naftchi '962 for example at col. 119, number 208, the same compounds are shown. All the claims require is the that the compounds are separate which they are before they are reacted.

Applicant continues to argue that the Naftchi patents show two ingredients which are not present together at the beginning of the reaction. Applicant points the examiner to example 1. First of all, both patents have more than one example 1. Naftchi '962, at col. 8, col. 18, and col. 130 all have an example 1. Thus, it is confusing which one applicant is talking about. Assuming applicant is talking about the example 1 at col. 8,

this example 1 is referring to table 1 reactions not the reactions in table 2 which the rejection is pertaining to. The example 1 in col. 8, refers to a reaction of a compound which is not even remotely related to the compound made in col. 119 of the Naftchi '962 patent. Further it is clear on col. 119, that the first column is the reactants which is why it says "reactants" and the second column says product. Thus, one of ordinary skill in the art would conclude that the first column was what was reacted. Secondly, the third "example 1" in col. 130 is what refers to the reactions in table 2. Clearly from this "example 1" it can be clearly seen that MBA is reacted with guanidine hydrochloride which is what table 2 says the reactants are which yields the product that table 2 says it does (see col. 119 under compound 208), thus the examiner is reading table 2 and the entire patent correctly contrary to the applicant's interpretation of the reference.

Thus, as the patents teach, the reactants are the same as the separated claimed product since they are first separate before they are mixed, thus anticipating the claimed invention.

Claim Rejections - 35 USC § 103

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Naftchi et al. '933, Naftchi et al. '962, Petrus, or Lai for the reasons of record and for the reasons which follow.

The teachings and arguments of the Naftchi references are discussed above.

Applicant argues that Lai teaches a conjugate of nitrogen oxide scavengers and dithiol carbamates and conjugates thereof which means that the reaction derived from the two has the same deficiency as the Naftchi patents. This is simply not true since alpha-lipoic acid is clearly taught as an antioxidant (col. 12, lines 55-end) and aminoguanidine is clearly taught as a nitric oxide synthase inhibitor (see col. 21, lines 45-55). Both of these are taught to be in a group of components to be used together to treat a disease. Applicants argue that the components are different but in the reference there is nothing to make one believe that the aminoguanidine and the lipoic acid are modified in any way, they are simply used in the same composition, thus they are at first, separated.

Applicant next argues that Petrus (see the claims) uses an aminosugar and therefore cannot teach the claimed invention since amino sugars are "the building blocks of our articular cartilage and have anti-inflammatory actions", but this does not matter. Applicant is claiming a product and as long as there is motivation to put the two components together which there is (see the claims) then the claims are obvious over the cited art of record.

In response to the language "consisting essentially of" in the claim, applicant is reminded of MPEP 2111.03:

For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by consisting essentially of' language.").

Applicants have not shown how any **other** ingredients that those which are claimed materially affect the fundamental characterisitics of the invention. Since aminoguanidine is an amino sugar, then how can it have a completely different activity from that of applicant's invention when applicant's invention encompasses aminosugars, namely aminoguanidine ?

Thus, the claimed invention is still obvious over the cited references.

Claims 1, 4 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moroz et al. (abstract, materials and methods, results).

Moroz teaches that L-nitroarginine methyl ester and DTT (dithiothreitol) are used together in the same buffered solution, see page 573, under "Results". Under "Materials and Methods" they state that the chemicals were supplied by Sigma and other chemical companies. Thus, the individual ingredients were in possession by the authors before they were combined. Thus, it would have been obvious for one of ordinary skill in the art to combine in a separate form the DTT (dithiothreitol) and the L-nitroarginine methyl ester since they were both going to be used in the buffered solution. Before they were combined to make the buffered solution they were together, thus forming the claimed composition of the ingredients being together but in separated form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael V. Meller
Primary Examiner
Art Unit 1655

MVM